

*REMARKS*

The amendments set out above and the following remarks are believed responsive to the points raised by the Office Action dated May 4, 2004. In view of the amendments set out above and the following remarks, reconsideration is respectfully requested.

Several changes have been made to the specification to improve its form. These changes correct obvious typographical errors and do not constitute the addition of new matter. For example, at page 23, lines 1-2, it is obvious that the mass of the coated particle is the mass (A) of the uncoated particle and the mass (B) of the coating membrane. It is also obvious on page 23, line 3, particularly in light of the ratio  $[B \times 100 / (A+B)]$  provided therein, that the specification should refer to the mass (B) of the coating membrane.

Claims 1-16 have been cancelled. Claims 17-30 are added by this amendment, to describe the invention more clearly. No new matter has been added, the basis for the amended claim language may be found within the original specification, claims, and drawings. For example, claim 17 is supported by original claim 14 and at page 19, line 23 to page 26, line 8. Claim 18 is supported, for example, at page 25, lines 22-25. Claims 19-30 are supported, for example, by original claims 2-4, 6-10, 12-13, and 15-16, respectively.

Claims 1-16 were rejected under 35 USC §102 as anticipated by JP 10-118557 to Tadao et al. (hereinafter referred to as "Tadao"). Claims 1-5 and 14-16 were rejected under 35 USC §102 as anticipated by U.S. Patent No. 4,891,223 to Ambegaonkar et al. (hereinafter referred to as "Ambegaonkar"). Claims 1-5, 8-10 and 15 were rejected under 35 USC §102 as anticipated by U.S. Patent No. 4,851,027 to Murayama et al. (hereinafter referred to as "Murayama"). Claims 1-4, 11 and 12 were rejected under 35 USC §102 as anticipated by U.S. Patent No. 5,955,104 to Momberger et al. (hereinafter referred to as "Momberger"). These rejections are each separately and respectfully traversed.

The presently claimed invention defines a method for producing a coated biologically active particle comprising a coating process (A) of applying a solution of a resin dissolved in a solvent to a surface of an uncoated particle containing a biologically active substance and forming a coated particle with a coating membrane by allowing the solvent to evaporate from the solution, and a degas process (B) of removing volatile substances from the coated particle by exposure to a hot draft to obtain a coated biologically active particle having a concentration of the volatile substances of 500 ppm or less with respect to the coated particles, wherein the volatile substances are solvents used at the time of the preparation of the coating membrane.

The presently claimed method provides significant advantages over the prior art. For example, as explained in the specification (page 25, line 25 to page 26 and Table 2) coated particles prepared using the inventive method including the degas process have concentrations of volatile substances well below 500 ppm, while coated particles prepared using a coating process of applying a solution of a resin dissolved in a solvent to a surface of an uncoated particle and forming a coated particle with a coating membrane by allowing the solvent to evaporate from the solution without the degas process have concentrations of volatile substances of as high as 3000 to nearly 7000 ppm. Another important benefit of the degas process is the effect on variability in the release function of the coated particle. As explained and illustrated in the specification (page 27 to page 30 and Table 3), coated particles prepared in accordance with the claimed method including the degas process (Examples 1-7) showed little change in the release function after a two week period compared to coated particles prepared without the inventive degas process (Comparative Examples 1-7) which showed a marked variation in release function with time.

None of the cited references disclose or suggest the presently claimed invention. For example, none of the cited references disclose or even suggest a method including applying a solution of a resin dissolved in a solvent to an uncoated particle including forming a coated particle with a coating membrane by allowing the solvent to evaporate from the solution *and* a degas process (B) to remove the volatile substances in the coated article to obtain a coated particle having a concentration of volatile substances of 500 ppm or less.

Neither Tadao nor Momberger disclose a degas process or even suggest removing volatile substances from the coated particle by exposure to a hot draft. There is simply no mention in Tadao or Momberger of the concentration of volatile substances in the coated particle, or any recognition of the important benefits of obtaining a coated particle having a concentration of volatile substances of 500 ppm or less.

The Examiner alleges that these references anticipate the claimed invention by merely allowing the solvent to dry or evaporate, alleging that this removes the solvent from the core and thus the ppm would be less than 500 and in fact it can be 0. Applicants respectfully disagree. For example, as shown in the specification, (page 25, line 25 to page 27, Table 2), the coated particles in Comparative Examples 1-7 which were coated using a coating process including applying a solution of a resin dissolved in a solvent and forming a coated particle with a coating membrane by allowing the solvent to evaporate from the solution but were *not* subjected to the claimed degas process have concentrations of volatile substances substantially greater than 500 ppm. In contrast, the coated particles in Examples 1-7 prepared

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in accordance with the claimed method including the inventive degas process have concentrations of volatile substances well below 500 ppm.

Accordingly, since Tadao and Momberger fail to disclose or even suggest a method of coating particles including a degas process to obtain a coated biologically active particle having a concentration of volatile substances of 500 ppm or less, the claims are patentable over these references.

The other cited references also fail to disclose or suggest the presently claimed invention. For example, neither Ambegaonkar nor Murayama disclose a coating process of applying a solution of a resin dissolved in a solvent, forming a coated particle with a coating membrane by allowing the solvent to evaporate from the solution, and a degas process of removing volatile substances from the coated particle by exposure to a hot draft. Thus, the claimed invention is patentable over the cited references.

For the reasons set forth above, reconsideration of the rejections is respectfully requested.

In view of the amendment and remarks recited herein, the application is considered in good and proper form for allowance, and the Examiner is respectfully requested to pass this application to issue.

If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,



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Shannon Schemel, Reg. No. 47,926  
LEYDIG, VOIT & MAYER  
700 Thirteenth Street, N.W., Suite 300  
Washington, DC 20005-3960  
(202) 737-6770 (telephone)  
(202) 737-6776 (facsimile)

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